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HOSPITAL TECHNICAL MEMORANDUM

SAFETY CODE FOR ELECTRO-MEDICAL APPARATUS

8

Department of Health and Social Security: London

Welsh Office: Cardiff

Hospital Technical Memorandum Number 8

Safety Code for Electro-Medical Apparatus

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I. Scope

1. This Memorandum has been drawn up to establish adequate standards in the design and construction of electro-medical apparatus for use in hospitals, with the aim of ensuring:

(i) Safety from electric shock to patients and to operators.

(ii) Safety from overheating and risk of fire in both the apparatus and its surroundings.

(iii) The provision of adequate and clearly marked controls.

(iv) That apparatus is conveniently accessible for servicing purposes.

2. The Code is applicable to new electrical apparatus used for diagnostic, therapeutic and other medical purposes. It covers portable apparatus which is intended for connection to an electrical supply having a voltage exceeding 15 V but not exceeding 250 V d.c. or r.m.s., a.c. and to fixed apparatus which is intended for connection to an electrical supply exceeding 15 V but not exceeding 450 V d.c. or r.m.s. a.c. across the line conductors and not exceeding 250 V to earth. It is also applicable to apparatus which is energised from self-contained batteries where the rated voltage or an internally generated voltage is capable of causing a harmful electric shock under any normal or fault conditions.

3. In general the precautions against electric shock are intended to safeguard against the risk of persons receiving an electric shock through the skin. In certain surgical procedures there is the possibility of electrodes or other metal parts of apparatus coming into direct contact with tissue or internal organs. Under these conditions the electric shock risk is considerably increased and special attention is drawn to this risk in the Code.

4. The aim has been to specify requirements in such a manner as to allow manufacturers the widest possible choice in design and construction. Where constructional details are specified to indicate minimum safety requirements, other forms of construction which will ensure an equivalent degree of safety under all conditions of normal use would be acceptable. Where electro-medical apparatus complies with a British Standard which deals specifically with that type of equipment, it can be considered as meeting the desired minimum standards of safety.

NOTE: Special safeguards concerning apparatus which may be used in the presence of flammable anaesthetics are not included. These are referred to in the Report of the Working Party on Anaesthetic Explosions [HMSO (price 2s. 6d.)]

II. Reporting of incidents

5. The proper investigation of unusual faults and incidents which concern the safety arrangements of any electro-medical apparatus can play an important part in bringing about improvements in the general safety standard of such apparatus.

6. Hospital Authorities are asked to co-operate by notifying the Department of Health and Social Security or the Welsh Office as appropriate, using the established defect reporting procedure (and in the case of Hospital Management Committees, the Regional Hospital Board) of all incidents involving the use of electro-medical apparatus in which the safety arrangements are suspected as being inadequate or otherwise unsatisfactory.

III. Definitions

For the purposes of this Safety Code the following definitions apply:

Apparatus

7. An electrically operated unit used for diagnostic, therapeutic or other medical purposes. The unit includes parts associated with it, such as fixed leads, inlet connectors and accessories including electrodes and leads forming connections to the operating unit during normal use.

Class I Apparatus (*earthed*)

8. Apparatus having exposed metal parts which are intended to be earthed.

Class IIA Apparatus (*all insulated*)

9. Apparatus having no accessible metal parts other than small parts such as screws and name plates which are separated from current carrying parts in such a manner than in normal use they cannot become " live ".

Class IIB Apparatus (double insulated)

10. Apparatus having exposed metal parts which are protected by extra insulation from current carrying parts. This extra insulation shall take the form of double insulation (functional insulation and protective insulation) except where it is necessary to use reinforced insulation.

Rated voltage or voltage range

11. The supply voltage or voltage limits assigned by the maker and marked on the apparatus.

NOTE: Voltages given in this Code are d.c. or r.m.s., a.c. unless otherwise stated.

Rated current

12. The supply current specified by the manufacturer when the apparatus is operated at maximum load whilst connected to a supply at the rated voltage or maximum voltage of a voltage range.

Rated frequency

13. The supply frequency specified for the apparatus by the manufacturer.

Rated output

14. Maximum output voltage, current or power when the apparatus is operated at the rated voltage and connected to an output load impedance in which the maximum output power is dissipated.

Leakage current

15. The maximum current which can flow between live parts and accessible metal parts (see paragraph 16) during the normal use of the apparatus.

Accessible metal parts

16. Electrically conductive parts which can be touched without the aid of a tool, including parts which can be touched before, during or after removal of interchangeable parts. Accessibility is judged by the application of standard test fingers as prescribed in B.S.3042 and additionally in Class II apparatus with a standard test pin (Figure 1). Small parts, e.g. nameplates, which are electrically isolated from other metal parts in such a manner that they cannot become " live ", are excluded.

Live parts

17. Electrically conductive parts operating at potentials exceeding 15 volts and so energised that contact with them may cause an electric shock current to earth (or to any other conducting part of the apparatus) in excess of 0.1 mA.

Interchangeable parts

18. Parts which can be removed or replaced without the use of a tool.

Functional insulation

19. The normal " working " insulation of live parts necessary for proper functioning and basic protection against breakdown, leakage and electric shock.

Protective insulation

20. A secondary layer of insulation interposed between functional insulation or functionally insulated metal parts and accessible metal parts that can be touched.

Double insulation

21. A method of insulation by which metal parts are separated from live parts by both protective and functional insulation.

Reinforced insulation

22. A type of improved functional insulation used only on parts of double insulated equipment where the principle of double insulation cannot reasonably be applied, and able to pass specified tests to ensure that at least an equivalent degree of safety is provided.

Earth free

23. Metal parts, conductors or circuit wiring completely electrically isolated from earthed conductors.

High frequency

24. Frequencies above 10 kc/s. (10 kHz).

Ultrasonic vibrations

25. Vibrations at a frequency exceeding 20 kc/s. (20kHz).

Clearance distance

26. The shortest distance in air between two conductors at different potential.

Creepage distance

27. The shortest distance over the surface of insulation between two conductors at different potential.

Portable apparatus

28. Apparatus which can be readily moved in normal use.

Fixed apparatus

29. Apparatus which is not moved in normal use and which is connected to its electrical supply by permanently installed wiring.

Totally enclosed apparatus

30. Apparatus protected by an enclosure without openings for ventilation but not necessarily air-tight.

Water-tight enclosure

31. An enclosure so constructed that it will exclude water under prescribed conditions which include a period of submersion.

Non-ignitable

32. Material which will neither burn nor give off flammable vapours in sufficient quantity to ignite when heated at a pilot flame, as prescribed in B.S.738.

Continuous duty apparatus

33. Apparatus capable of operating continuously within the specified temperature limits and without harm during normal use.

Intermittent duty apparatus

34. Apparatus which is suitable for operation for a limited period of time only after which a recovery period is necessary.

Operating temperature

35. When operated at the rated voltage and rated current, the maximum temperature at the test point when steady temperature conditions have been reached.

Ambient temperature

36. The temperature of the test room to be measured 3 ft. (0.914 m.) from, and at the same height as, the test position. Where necessary, the thermometer used shall be shielded against possible radiated heat and draughts.

Temperature rise

37. The difference between the operating temperature and the ambient temperature.

Thermostat

38. A device which includes a temperature sensitive element in order to maintain a predetermined temperature.

Thermal cut-out

39. A device incorporating a temperature sensitive element which operates contacts so as to limit the temperature to a predetermined value. The device requires to be manually re-set.

Connector

40. A device, incorporating contacts and arranged for attachment to a flexible cord, for connecting portable electrical appliances to the supply by insertion into an appliance inlet.

Appliance inlet

41. A device to receive a connector, which incorporates pins and is mounted on, or forms an integral part of, the portable electrical appliance.

Fusing factor

42. The ratio between the minimum fusing current and the current rating of a fuse, i.e.

$$\frac{\text{Minimum fusing current}}{\text{Current rating}}$$

IV. Tests

Type tests

43. The tests specified in the Code are intended to be type tests. To prove compliance with the Code a representative sample of each type of apparatus in new condition shall be subjected to the tests. Normally the tests will be carried out by the manufacturer of the apparatus. Alternatively a competent testing authority may be commissioned to carry out the tests on behalf of the manufacturer.

44. Except where a higher test voltage is specified for specific tests, apparatus shall be tested at the rated voltage or at the maximum voltage where an inclusive voltage range (e.g. 200–250 V) is marked on a nameplate. Where operating controls and interchangeable components are provided, the tests shall be made with the controls in the most unfavourable positions and with the components fitted which will prove the most exacting to the apparatus.

45. Apparatus which is designed for both a.c. and d.c. shall be tested using the type of current which will prove most exacting.

46. Apparatus shall be capable of complying with the tests in any ambient temperature within the range of $20 \pm 5^{\circ}$ C, except that where special temperature limits are specified it shall be capable of complying with the tests within the stated limits.

47. Measurements shall be made with instruments which will not themselves appreciably affect the value to be measured.

48. To comply with the Code the sample shall pass all relevant tests.

49. In the event of failure, all tests shall be carried out again after necessary remedial action has been taken.

Routine tests

50. In addition to the type tests on selected units referred to in paragraph 43, manufacturers shall carry out routine tests on all apparatus to prove the adequacy of essential insulation and earth continuity (where applicable) in addition to any tests necessary to prove the functional requirements of the apparatus.

V. Safety Code

General construction

51. The construction of apparatus shall be such that when properly used for the purposes intended, there shall be no danger to the patient, operator, or to the surroundings. It shall be sufficiently robust, workmanlike and corrosion resistant to withstand, without any reduction of safety factors, the mechanical stresses, heating, cooling, humidity, sterilization and disinfecting (where applicable) likely to be encountered in normal use.

52. As far as is practicable, apparatus shall fail to safety i.e. shall be so designed and constructed that any fault occurring on any component part, wiring, etc. will not create conditions which can affect its safety in use.

53. Enclosures housing live parts including any access covers forming part of enclosures shall be capable of withstanding an inward directed pressure of 10 lb. (4.5 kg.) applied over an area of 1 square inch (645 mm.^{2}) anywhere on the surface without showing appreciable damage or reducing protective clearances below the minimum values specified.

54. Apparatus which incorporates liquid containers shall be so constructed that spillage of liquid either in normal use or during filling or emptying procedures shall not affect the safety of the apparatus.

55. Non-ignitable and non-absorbent materials shall be used where practicable.

56. Access covers which are necessary for safety shall be secured by screws that engage at least three complete threads or by mechanical type fasteners, so that access to live parts which operate at voltages exceeding 15 V can be obtained only with the aid of a tool. When fasteners or four or less screws are used for this purpose they shall have a captive device to prevent them from becoming detached from the cover. Self-tapping screws shall not be used for access covers which are likely to be removed during routine servicing.

57. Assemblies shall not be affected by vibration experienced during normal use.

NOTE: On complex apparatus the provision of monitoring points is desirable to enable voltage, current or waveform measurements to be made.

Oxygen tents and baby incubators

58. There shall be complete fire resisting separation between electrical components and parts of the apparatus in which there may be an oxygen enriched atmosphere.

Hyperbaric oxygen chambers

59. These chambers may be pressurised with oxygen up to 3 atmospheres (30 p.s.i.—2 bar) and the effect of increased pressure is to increase the fire risk still further, also in an emergency it will take an appreciable time to remove an occupant, so that the most stringent fire precautions to avoid ignition are necessary in and around hyperbaric oxygen chambers.

Electric equipment

60. Electric wiring and equipment in the chambers should be restricted to the absolute minimum necessary. Transducers for physiological monitoring should preferably be of a self-energised type and means adopted to limit the circuit current which can flow under any fault conditions to a few milliamperes and the maximum potential difference to about 0.5 volts peak. Where it is necessary to supply electrical power to circuits within the chamber, e.g. for communication, the maximum power which can be dissipated should be kept to the absolute minimum for satisfactory operation, the peak circuit voltage should not exceed 1 volt and the energy should not exceed 100 milliwatts even under fault conditions. This will reduce the risk of incendive sparking. As a further safeguard, wiring for power-dissipating circuits should be fixed and have non-flammable type insulation.

Anti-static precautions

61. Although anti-static precautions are not considered to be necessary in oxygen enriched atmospheres at normal pressures unless there is the possibility of a flammable gas or vapour also being present, because of the increased hazard arising from pressurised oxygen enriched atmospheres, full anti-static measures should be taken in the chamber as recommended for anaesthetising areas (see Hospital Technical Memoranda No. 1, Anti-static Precautions: Rubber, Plastics and Fabrics and No. 2, Anti-static Precautions: Flooring in Anaesthetising Areas).

Fire precautions

62. See Hospital Technical Memorandum No. 16 (Revised 1969).

Enclosures for apparatus supplied at voltages up to 250 V

63. The construction of enclosures for apparatus which is supplied at potentials not exceeding 250 V shall be one of the following:

(i) Earthed metal which is electrically continuous (Class I);

(ii) Insulating material (Class IIA);

(iii) Metal having double insulation or reinforced insulation separation from live parts (Class IIB).

Enclosures for apparatus supplied at voltages exceeding 250 V

64. Enclosures for apparatus which is supplied at potentials exceeding 250 V shall be totally enclosed in earthed metal which is electrically continuous and adequately protected against mechanical damage or be so constructed and protected as to provide an equivalent degree of safety.

Earthing of metal parts (Class I apparatus)

65. Accessible metal parts shall be so constructed that they are provided with a permanent and reliable earth continuity path to the main earth terminal. The resistance of each earth path on the apparatus shall not exceed 0.1 ohm and it shall be capable of carrying a current of 25 A for a period of at least 5 seconds. The requirements of this clause shall not apply to metal parts or screws in or through insulating materials and separated from current carrying parts in such a manner that they cannot become live or come into contact with earthed parts.

NOTE: A test voltage not exceeding 6 V is recommended for earth continuity tests.

66. The main earth terminal shall be of non-corroding material and be conveniently located near the main supply terminals. It shall have a current carrying capacity at least equal to that of the largest earth continuity conductor. The earth terminal shall not be used for securing any component and it shall not be possible to loosen the earth connection without the use of a tool.

NOTE: It is recommended that the main earth terminal be not smaller than 2 B.A. or its equivalent, except where a fuse rated at 2 A or less is incorporated in the apparatus when a 4 B.A. screw or its equivalent may be used.

67. Where an appliance inlet forms the supply connection to the apparatus the earth pin of the connector shall be regarded as the main earth terminal.

68. Earth continuity conductors incorporated in the same sheath as the supply conductors shall have a current-carrying capacity at least equal to that of the live conductors. Separate earth continuity conductors shall be equal to the largest current-carrying conductor on the apparatus but shall not be smaller than 40/.0076 in. (30/0.25 mm.) copper (or have equivalent current-carrying capacity if other types of conductors are used).

69. Where plugs and sockets are provided for disconnecting supply conductors the connections shall be so arranged that the earth connection is made and broken with the live conductor connections.

Class II (A and B) Apparatus (all insulated and double insulated apparatus)

70. Live parts shall be protected by insulation having adequate mechanical strength, and capable of complying with the relevant requirements of paragraphs 98 to 104. On Class IIB apparatus the protection shall consist of functional and protective insulation. Reinforced insulation shall be used only where double insulation is not practicable, e.g. on connectors, plugs, sockets and other terminal devices. Air spacing alone is not acceptable for isolating live parts from accessible metal parts unless the positioning is such that bridging between the live parts and exposed metal is completely precluded.

71. Internal wiring and other live conductors shall be so secured and/or the inner surfaces of exposed metal parts shall be protected with insulation, to prevent any possibility of live conductors coming into contact with exposed metal parts in the event of an accidental disconnection.

72. The design shall be such that it is impossible for protective insulation to be made ineffective by leakage paths caused by accumulated dust, grease, oil, etc.

73. Capacitors shall not be connected to accessible metal parts of Class IIB apparatus.

74. Except where necessary for functional purposes, earth terminals shall not be provided nor shall the supply flexible cord contain an earth continuity conductor. Where an earth connection is necessary for functional purposes the earth terminal and earth continuity conductor shall be effectively insulated from accessible metal parts.

Protection against electric shock

75. All live parts shall be protected to prevent accidental electric shock when the apparatus is being properly used for the purpose for which it is intended. This requirement shall be complied with when interchangeable parts are removed but is not applicable to live parts which must be accessible for the proper operational use of the apparatus. Apparatus shall be so designed, however, that the risk of electric shock resulting from abnormal or careless operation is obviated as far as practicable. Non-accessibility of live parts shall be checked by means of test fingers A and D prescribed in B.S. 3042 Additionally non-accessibility of live parts through holes in insulating material and in unearthed metal is checked by the test pin shown in Figure 1.

76. Any non current-carrying metal parts which may come into direct contact with patients and which cannot be reliably earthed, e.g. the rotating parts of surgical saws and drills, shall be separated from any conductors which are liable to operate at potentials exceeding 15 volts, by double insulation appropriate to the maximum working or fault voltage or equivalent reinforced insulation where double insulation is not practicable, or other equivalent electrical separation.

77. Leakage current between the mains supply circuit and the output (patient) circuit shall not exceed 0.1 mA. on equipment that may be used with wire electrodes

inside the heart, such as pacemakers, thermistor probes, intra-cardiac phono transducers etc. When testing for leakage current any earthing connection on the apparatus shall be disconnected; Figure 2 shows a schematic diagram of the test circuit.

78. Capacitors which are connected between the power supply and exposed metal parts shall comply with B.S. 2135. For equipment which may have direct electrical connection to the patient the maximum leakage current through such capacitors under the most adverse conditions of normal use shall not exceed 0.1 mA. For other equipment the maximum leakage current under similar conditions shall not exceed 0.5 mA.

79. Varnishing, enamelling, oxidation and similar protective finishes shall not be regarded as providing protection against electric shock.

NOTE ON ELECTRIC SHOCK: The value of electric current, flowing in the body, which causes a given degree of stimulation, varies from individual to individual. Typical threshold values of current to produce certain responses where the current flows into the body from external contacts, e.g. hand to hand are:

Response	a.c.	d.c.
Threshold of feeling	1 mA	5 mA
Muscular paralysis	15 mA	75 mA
Ventricular fibrillation	70 mA	300 mA

If connection is made directly to the heart, however, the danger of ventricular fibrillation is considerably increased and experience has shown that this can occur with currents as low as 0.5 mA.

Terminal connections

80. Materials, design and proportions of all connections shall be such that they will not slacken or overheat under normal conditions of use. They shall take the form of screwed, soldered, welded or plug and socket connections.

81. Screwed connections shall ensure that conductors connected thereto are effectively clamped between metal surfaces and contact pressure shall not be transmitted through any material that is liable to yield or deteriorate in normal use. The pressure from any nut or screw used for clamping a conductor shall not be used for clamping any other component.

82. The siting and arrangement of terminals shall permit easy insertion and connection of conductors, and the spacing of terminals shall ensure that the specified minimum clearance and creepage distances specified in paragraphs 99–101 are obtained when proper connection is made with terminals at full capacity.

83. Terminal screws and nuts shall be of metal, and engage for a length equal to at least three times the pitch of the screw. Self-tapping screws, and screws or terminals made of aluminium, zinc or zinc base alloys shall not be used for any form of electrical connection. Where connections are secured by a nut or screw head, a locking nut or locking type washer shall be used, and eyelets, or other means of preventing the strands on the conductors from spreading at the terminals, shall be used.

84. In pillar-type terminals the screws shall be of sufficient length to extend to the far side of the terminal hole and shall be of a diameter approximately equal to that of the hole. The ends of the screws shall be rounded or chamfered to prevent damage to the conductors, and the side of the hole against which the conductor bears shall be smooth and unbroken.

85. Live parts of terminals shall be enclosed in insulating material sufficiently to prevent accidental contact and electric shock. The insulation of terminals and joints shall be not less than that of wiring connected thereto.

86. Connectors which are designed to accommodate more than two conductors shall be fixed in such a manner that they remain secure when the connections are tightened or slackened.

87. Separate mechanical type connectors for single conductors may be supported by the wiring provided that they are capable of withstanding the mechanical, thermal and electrical stresses occurring in normal use without loosening, and that the live parts are shrouded with material having insulating properties at least equal to that of the wiring.

88. Mains input terminals shall be conveniently accessible and shall be marked to indicate the correct polarity, i.e., " L " for the line terminal and " N " for the neutral terminal. The main earth terminal shall be located conveniently near the mains input terminals and marked " E ". It may also be marked with the international symbol ⏚. Where more than two supply terminals are provided, the voltage rating of each terminal shall be clearly and indelibly indicated on or near the terminals. It shall not be possible to change the voltage setting without the use of a tool.

89. Appliance inlets shall comply with a relevant British Standard. Any plug or socket connections or couplers shall comply with an appropriate British Standard or with the safety requirements of this Code.

Internal wiring

90. Wiring and other current-carrying parts shall have a current rating at least equal to the maximum steady current which is likely to flow in normal use and the maximum operating temperature of the insulation shall not exceed the value given in paragraph 212 for the material used.

91. Wiring between components mounted in the apparatus which operate at mains potential and wiring in any circuit to which patients may be connected, shall have conductors not smaller than

14/.0076 in. (16/0.20 mm.) and these shall be insulated as far as is practicable. Such wiring shall comply with a relevant British Standard. Except as provided for in paragraph 92, other internal wiring between components shall be insulated and be not smaller than 7/.0076 in. (7/0.20 mm.) and shall comply with an appropriate British Standard or other approved specification.

92. Bare single wire conductors not smaller than 0.028 in. (0.75 mm.) (22 S.W.G.) may be used for short connections between rigidly mounted components which are not likely to be subjected to stress and/or vibration in normal use.

93. All components shall be secured and supported independently of the wiring, except for small components weighing less than ½ oz. (14 grms.) which may be secured by their leads provided that these leads are not more than 1½ in. (38 mm.) in length and there is at least ⅛ in. (3 mm.) of straight lead leaving the component in its normal line before a bend is made in the lead. Components secured only by their leads shall be connected direct to fixed terminal points, a free joint between wiring and a component shall not be permitted.

94. All wiring shall be laced and secured or otherwise so arranged that uninsulated ends of conductors are prevented from coming into contact with other conductors or with accessible metal parts in the event of any conductor loosening or fracturing, if such contact would give rise to a hazard. Internal wiring shall not be secured to access covers which are liable to be removed during routine servicing.

95. Conductors of the under-mentioned circuits shall be separately laced, or otherwise secured and separated to prevent any possibility of accidental connection between them. Special care shall be taken to insulate the following circuits from earthed metal parts:

(i) Wiring of circuits incorporating parts which may come into direct metallic contact with patients during the proper operation of the apparatus.

(ii) Wiring which is directly connected to the power supply.

(iii) Other wiring which operates at potentials capable of causing a harmful electric shock.

96. Wiring which operates at voltages in excess of 15 V shall have a protecting layer of insulation appropriate to the maximum working voltage in addition to the functional insulation where it passes through metal parts or where it passes over a sharp edge or elsewhere where relative movement is liable to damage the functional insulation.

97. Any enclosure which houses wiring shall be smooth and free from sharp edges, burrs, etc., such as may cause damage to insulation.

Insulation

98. Insulation necessary for the safety of the apparatus shall be capable of complying with the specific electric strength, insulation resistance, leakage current, humidity and temperature tests and shall be arranged so that the minimum creepage distances and air clearances are complied with.

Creepage distances and air clearances and distances through insulation

99. Creepage distances, air clearances and distances through insulation shall not be less than the values given in the table below.

	Class I Apparatus	*Class II Apparatus*
	inches (mm.)	inches (mm.)
A. *Creepage distance or air clearance for conductors having electrical connection to a patient*		
(1) Where voltages do not exceed 1,400 V peak		
(*a*) Between bare conductors in the patient circuit and bare conductors connected to the supply mains	1 (25·4)	1 (25·4)
*(*b*) Between bare conductors in the patient circuit and other bare live parts ..	½ (12·7)	½ (12·7)
(*c*) In apparatus which operates with an " earth free" connection to the patient; between bare conductors in the patient circuit and bare conductors which are earthed or are connected in an earthed circuit	½ (12·7)	½ (12·7)
*With components complying with a British Standard or other approved specification these values may be reduced, for example, at the connections to a valve base, provided that means shall be provided (e.g. overall insulated sleeving) to ensure that no accidental bridging of the reduced clearance can take place.		
(2) Where voltages exceed 1,400 V peak	The above values shall be increased, if necessary, to twice the minimum creepage distances and air clearance required to prevent brush discharge.	
Note.—Smaller creepage distances and clearances are permissible where a short circuit across the clearance cannot cause harm to the patient or user.		

	Class I Apparatus	*Class II Apparatus*
	inches (mm.)	inches (mm.)
B. *Creepage distance or air clearance for other conductors*		
(1) Where voltages do not exceed 354 V peak		
†(*a*) Between bare live parts at different potentials	$\frac{1}{8}$ (3·2)	$\frac{1}{8}$ (3·2)
†(*b*) Between bare live parts and other metal parts separated by functional insulation only	$\frac{1}{8}$ (3·2)	$\frac{1}{8}$ (3·2)
(*c*) Between bare live parts and the inner surface of protective insulation of Class IIB apparatus	—	$\frac{1}{8}$ (3·2)
(*d*) Between bare live parts and other metal parts separated by double or by reinforced insulation	—	$\frac{3}{8}$ (9·5)
(*e*) Between metal parts separated by protective insulation or between accessible metal parts and the outer surface of functional insulation	—	$\frac{1}{4}$ (6·4)
(*f*) Between live parts and metal foil wrapped round the outer surface of Class IIA apparatus	—	$\frac{1}{4}$ (6·4)
†These values do not apply to components such as switches, lampholders, valve bases, etc., which comply with a relevant British Standard or other approved specification nor to the clearance between switch contacts.		
(2) Where voltages are greater than 354 but do not exceed 1,400 V peak	The above clearances shall be increased by an amount equal to $\frac{E-354}{5}$ per cent of the above values, where E is the peak working voltage.	
(3) Where voltages exceed 1,400 V. peak	The above values shall be increased, if necessary, to twice the minimum creepage distance or air clearance required to prevent brush discharge.	
C. *Distances through insulation*		
‡(*a*) Between metal parts separated by protective insulation	—	0·04 (1)
‡(*b*) Between metal parts separated by reinforced insulation	—	0·08 (2)
(*c*) Between live parts and the test finger, referred to in paragraph 16, when this is applied to any point on the enclosure of Class IIA apparatus	—	0·08 (2)
‡These items may consist of a layer of insulation which passes the electric strength test appropriate to the working voltage (paragraph 104) plus one or more air gaps. They may be reduced if two or more separate layers of insulation are used provided that each layer individually passes the appropriate electric strength test for the whole.		

100. In determining creepage distances the surface distance of grooves of $\frac{1}{16}$ in. (1.6 mm.) or less in width shall be ignored and the creepage distance measured across the groove. Where the clearance distance consists of two or more air gaps in series, any gap of less than $\frac{1}{32}$ in. (0.8 mm.) shall be ignored.

101. For high-frequency components and insulation used in conditions where the deposition of dust or moisture may occur, the creepage distance, minimum air clearance and distance through insulation shall be increased, if necessary, to avoid the risk of insulation failure.

Insulation resistance

Apparatus having a rated input voltage not exceeding 250 V

102. The insulation resistance shall be measured by applying a test voltage of approximately 500 V d.c. between the points specified below:

(i) Between the conductors of circuits directly connected to the supply source with the switch contacts open.

(NOTE: This test is applicable only to apparatus having a switch controlling the power supply.)

(ii) Between the input terminals connected together and any output terminal devices.

(NOTE: This test is not applicable to battery-operated equipment.)

(iii) Between live parts of the supply circuit and accessible metal parts.

(iv) Between live parts of earth-free circuits and accessible metal parts.

(v) Between live parts and metal foil arranged in intimate contact with exposed parts of insulating material.

(vi) Between functionally insulated metal parts and exposed metal parts or metal foil arranged in intimate contact with exposed insulated parts on Class IIB apparatus.

(vii) Between live parts and inaccessible, functionally insulated metal parts on Class IIB apparatus.

(viii) As necessary to test other insulation, the breakdown of which could affect the safety of the apparatus.

(ix) For transformers, measurements shall be made between each winding and each remaining winding in turn, between each winding and each earthed screen and between each winding and frame or core.

The resistance shall be not less than 10 megohms.

Apparatus having a rated input voltage exceeding 250 V

103. The insulation resistance tests (i)–(viii) above shall be carried out as appropriate using 1,000 V d.c. (nominal test voltage). The test results shall be not less than 10 megohms.

Electric strength test

104. Insulation shall be subjected to an alternating test voltage as specified below and no flash-over or breakdown shall occur during the test. The voltage shall have an approximately sinusoidal waveform of 50 cycles per second and for test potentials exceeding 500 V it shall be increased gradually over a period of 10 seconds from 500 V to the final value specified below, which shall be held for one minute. The transformer used for the test shall have a capacity of at least 50 VA.

NOTE: Transformers are exempt from the electric strength test.

Class I Apparatus

(i) Insulation which will be subject to a maximum voltage of 30 V in normal use .. .. .. 500 V

(ii) Insulation which has to withstand more than 30 V but not exceeding 250 V during normal use .. 1,500 V

(iii) Insulation which has to withstand potentials exceeding 250 V in normal use .. .. .. 2 × V MAX + 1,000 V

where V MAX is the maximum rated voltage of the component or apparatus.

Class II Apparatus

Both functional and protective insulation shall be capable of withstanding the test voltages specified above and the following additional tests shall be made:

(iv) Between metal parts which can be touched, or foil arranged in intimate contact with exposed insulating surfaces and the electric supply conductors 2 × Vt, where Vt is the test voltage specified above.

NOTE: Where the test voltage is applied to opposite poles of a microgap switch and the contact clearance is insufficient to prevent a flashover, the clearance may be increased, e.g. by inserting suitable insulation between the switch contacts.

Humidity test

105. Apparatus, including any detachable component parts, which is liable to be subjected to high humidity conditions in service, particularly those which are liable to be sterilized, shall be sufficiently proof against the effects of humidity and shall be capable of withstanding the following test:

(i) The apparatus shall be placed in a humidity chamber at 85–90% r.h. for 24 hours. The temperature of the humidity chamber shall be kept substantially constant at a value approximately equal to the ambient temperature of the test room. Before being placed in the humidity chamber the appliance shall be maintained at the same temperature as the humidity chamber for five hours.

(ii) The apparatus shall be capable of withstanding the appropriate electric strength test immediately after being removed from the humidity chamber.

Switches

General

106. Switches shall be provided on fixed apparatus and on portable apparatus which is designed for use with electrodes or other metal parts which are likely to come into direct contact with patients during normal use. In these circumstances the switch shall be arranged to interrupt each supply conductor and the "ON" and "OFF" positions of the switch shall be clearly indicated or alternatively an indicator lamp shall be provided as specified below. Switching of power supply conductors on other portable apparatus operating at potentials up to 250 V is optional. Where switching of the power supply conductors is omitted, an indicator lamp complying with paragraphs 179–181 shall be provided in a conspicuous position and arranged to indicate when the apparatus is "live".

107. Apparatus operating at potentials exceeding 250 V, including those which incorporate a step-up transformer having an output voltage exceeding 250 V, shall incorporate a switch which shall be arranged to isolate each supply conductor from the electricity supply.

108. Switches controlling power supplies and other switch contacts which are associated with the safe operation of the apparatus shall have adequate mechanical strength and current making and breaking capacity to function repeatedly without undue deterioration or temperature rise. They shall be so designed that the operating parts come to rest in the "on" and "off" positions only and where necessary the switch mechanisms shall be protected against mechanical damage. The switching action and the location of the switch contacts shall be independent of any detachable cover.

109. Switches for d.c. operation shall have a quick make and break action. Switches for a.c. operation shall be so constructed that no undue arcing will occur when the switch is operated slowly.

110. Knobs, push-buttons and other switch operating mechanisms which are intended for manual

operation shall be constructed of insulating material or if of metal shall have an earthing connection complying with paragraph 65 or shall be protected by double or reinforced insulation from live parts. Other accessible metal parts which may become live in the event of an insulation failure shall be provided with a permanent and reliable connection to the main earth terminal.

111. Terminals on switches shall comply with the relevant parts of the Safety Code.

112. Switches shall not be incorporated in flexible supply cords or other flexible leads between components.

113. Relays and similar devices which rely on an energising current for their operation and which can affect the safety of the apparatus shall be so arranged that their circuits are in the " off " or safe position when the operating coil is de-energised.

Switch endurance test

114. Switches shall comply with a relevant British Standard or shall be capable of satisfying the following endurance test without electrical or mechanical failure or undue pitting or burning of contacts.

115. Switches shall be operated 20,000 times (20,000 makes and 20,000 breaks) at a rate not exceeding 30 operations per minute, making and breaking the rated current whilst connected to a supply at a rated voltage. Where the switch contacts are adjustable they shall be adjusted to the least favourable setting.

116. Rotary switches which operate in both directions shall be tested so that half of the number of operations are in one direction and the other half in the reverse direction.

Foot-operated switches

117. Switches which are intended for foot operation shall be of robust construction and be so arranged that excessive foot pressure is not transmitted to the switch mechanism. Switch contacts shall be of adequate making and breaking capacity for their functional use and shall be capable of complying with the switch endurance test without mechanical or electrical failure, or undue burning or pitting of contacts.

NOTE: Because they are particularly liable to damage it is desirable that foot-switches should be operated at a low voltage, e.g. 6 V.

118. Foot-switches having a rated voltage exceeding 15 V which are liable to be used in situations where water may be present shall be of watertight construction and this shall include the cable entry into the switch.

119. The flexible cord connection to the foot-switch and the cord anchorage at the entry point to the switch shall comply with the requirements specified for flexible supply cords in paragraphs 169–172.

120. Plug and socket connectors used with foot-switches shall comply with the appropriate parts of the code and detachable parts of connectors shall not fit into any standard mains type of socket or with any socket on the apparatus which operates at a higher potential. Where incorrect connection can constitute a danger, a mechanical interlock shall be provided to prevent this.

121. Where more than one foot-switch is provided with any one unit and each has a separate function, each shall be clearly marked to indicate its functional use and so reduce the possibility of incorrect operation.

122. Conductors and components operating at voltages exceeding 250 V or at high frequencies shall not be housed in foot-switch enclosures.

Pressure-operated switches

123. Pressure-operated switches shall have adequate making or breaking capacity and shall comply with an appropriate British Standard or with the relevant parts of the Safety Code including the switch endurance test. They shall be capable of operating reliably within the pressure limits necessary for the safety of the apparatus.

Time switches

124. Where the correct duration of treatment is important for therapeutic purposes an accurate and reliable timing control shall be provided together with an audible and/or visual indication of the switching time. Where the operating time is fixed it shall be clearly indicated on the apparatus, close to the operating controls. Timing circuits shall be arranged to fail safe in the event of a component failure.

125. Time switches, including relays and electronic devices used to control the duration of treatment currents, shall be clearly and indelibly marked to indicate the time setting and shall operate within an accuracy of ± 10 per cent of the indicated value over the complete timing range. They shall have adequate current making and breaking capacity and comply with a relevant British Standard or with the relevant parts of this Code including the switch endurance test.

Arrangement of controls

126. All controls shall be clearly and indelibly labelled to indicate their proper function, the marking to include " ON ", " OFF " positions, minimum and maximum positions. The direction of rotation for intensity controls is to be clockwise to increase output.

127. Controls and instruments which indicate the output of the apparatus shall be clearly marked to

show the correct output setting and be accurate to within ±10 per cent of the indicated value throughout the scale or range.

128. Controls, instruments, indicating lamps, etc., which are associated with a separate function of the apparatus shall be grouped together and their function clearly labelled to reduce the possibility of inadvertent misadjustment of controls. Where the misadjustment of controls can constitute a danger, appropriate steps shall be taken to reduce this possibility, e.g. by an interlocking device or an additional safety control.

129 Handles, knobs, etc., shall be made of insulating material except that metal parts may be used where they cannot become " live " under any foreseeable fault conditions, e.g., loosening of wires, screws, etc.

130. Knobs, etc. whose adjustment can affect the safety of the apparatus in use shall be so secured that it is not possible to rotate them without the shaft, under any conditions which are liable to occur in normal use. It shall not be possible to fix them in the wrong position relative to the " ON ", " OFF " or scale markings.

131. Operating shafts and other metal parts forming the operating mechanism of controls shall not be part of the current-carrying circuit and shall be effectively insulated from live parts.

132. Stops shall be provided on rotating or movable parts of controls, where necessary, to prevent damage to wiring, etc.

Temperature control

133. Thermal safety devices shall be provided where necessary to prevent operating temperatures exceeding the limits specified in paragraphs 210–212. Where overheating can constitute a danger to the patient at least two separate temperature limiting devices shall be provided, one of which shall be pre-set to operate at a predetermined safe temperature and shall be either of a type which has to be reset manually or be arranged to operate an audible and/or visual warning device when the maximum safe temperature is exceeded. The temperature of operation of the pre-set device shall be above that normally attainable at the maximum setting of the normal control device. It shall not be possible to change the setting of this pre-set temperature limiting device without the use of a tool. Apparatus which incorporates a fluid container having heating facilities shall be provided with a thermal safety device to safeguard against overheating in the event of the heat being switched on with the container empty.

134. Thermostats, thermal cut-outs and relays which function during the normal temperature control of apparatus shall comply with a relevant British Standard or other approved specification or shall be capable of satisfying the following tests:

(i) The thermostat or relay (in conjunction with its heat sensitive element) shall be operated thermally 500 times at its rated voltage and current, the operating rate being not slower than is likely to be encountered during normal use in the apparatus. The temperature control during the tests shall be within the limits necessary for the safe use of the apparatus.

(ii) In addition to the thermal tests described in (i) the switch contacts associated with the thermostats or relays shall be capable of complying with the switch endurance test described in paragraph 115 without electrical or mechanical failure, or undue pitting or burning of contacts.

135. Where means are provided for varying the temperature setting of thermostats the temperature range shall not exceed that which is necessary for the proper functioning of the apparatus and the temperature setting shall be clearly indicated. The operating temperature of pre-set temperature controls shall be clearly indicated.

Heating elements

136. Heating elements shall be totally enclosed in a protective metal sheathing or, where lamps are used as a heating source, they shall be enclosed or guarded to protect against mechanical damage and accidental contact with hot surfaces.

137. The maximum operating temperatures of exposed surfaces of guards or enclosures shall not exceed the temperature limits specified in paragraph 211.

138. The maximum wattage loading of heating elements or lampholders designed for use with heating lamps shall be clearly and indelibly indicated near the heater or on the name plate of the apparatus.

Transformers

139. Transformers having a rated voltage exceeding 15 V shall comply with the relevant parts of this Safety Code. Transformers which are connected between the electric supply and any circuit to which the patient may be connected, or any circuit containing components which may come into direct contact with patients, shall also comply with requirements (i)–(xiii) below.

(i) One of the following methods shall be used to separate primary and adjacent secondary windings, also to separate any winding in a circuit to which the patient may be connected from any other winding which operates at more than 15 V to earth:

(*a*) wound on separate bobbins.

(*b*) wound on one bobbin with an imperforate insulting partition between windings.

(*c*) wound on one bobbin with the windings overlapping one another and having an imperforate copper or tinned copper screen at least 0.003 in. (0.1 mm.) thick between them, the screen having an earth connection of at least 14/.0076 in. (16/0.20 mm.) The insulation between the windings and the earth screen shall be at least 0.010 in. (0.3 mm.) thick.

(ii) The insulation between windings and between the windings and the core or the earth screen (where provided) shall be capable of complying with the electric strength test described in paragraph 104 appropriate to the maximum voltage of the windings concerned.

(iii) Where the transformer winding consists of 22 S.W.G. (0.75 mm.) wire or heavier, the same wire may be used for connections to terminals located on the transformer, but the wire shall be covered with insulating sleeving. Windings of smaller diameter shall terminate with flexible "tails" not smaller than 14/.0076 in. (16/0.20 mm.) for mains and patient circuits, and not smaller than 7/.0076 in. (7/0.20 mm.) for other circuits, the wire having integral insulation.

(iv) Connections to terminals must be made by wrapping the wire round the terminal, or looping through a hole so that the joint is mechanically strong, independently of the solder.

(v) Terminals and connections to primary and secondary windings shall form an integral part of the transformer assembly and be arranged to provide the degree of physical separation set out in paragraph 99. They shall not be located on the outer covering of the windings.

(vi) Each secondary winding shall be electrically isolated from the primary and from any other secondary windings and shall have only one set of terminals. Terminals and connections to primary and secondary windings shall preferably be located on opposite sides of the transformer. The physical separation shall not be less than that specified in paragraph 99.

(vii) Transformer windings, connections and terminals which are not housed in a total enclosure shall be fully shrouded with non-ignitable materials.

(viii) Bobbins, central tubes and end cheeks shall be fabricated or moulded from insulating materials which will withstand a continuous working temperature of 110° C as well as the heating associated with the impregnating process, without softening or deteriorating. Before use, all formers and bobbins shall be clean and free from burrs and blemishes. All lead holes shall have their edges slightly rounded. Preferably, the lead holes should be the minimum size to accommodate the particular lead out wires. Where the radial depth of coils cannot be maintained accurately, radial slots may be provided instead of holes.

(ix) Only thoroughly dry wires shall be used. All windings shall be continuous and without joins as far as practicable. Joints shall be adequately insulated and the insulating materials shall be secured by successive turns and not by adhesive.

Windings shall be laid axially in layers and have insulation between layers where necessary to comply with paragraph 139(xi). Each layer shall be laid evenly under constant tension, shall be free from crossed, slack, kinked or buckled wires and shall be only one wire deep. Inter-leaving insulation, where provided, shall ensure adequate bedding down and extend the full width of the bobbin. Some mechanical means, such as folding the edges of the paper, shall be used to prevent displacement of the end turns.

Complete coils which are spongy or over size must not be compressed to make them usable but shall be rejected.

(x) The following types of conductor covering shall be used for windings:

(*a*) cotton to B.S.1791;

(*b*) Enamel to B.S.156, B.S. 1844 or B.S.3188 medium thickness;

(*c*) Enamel and rayon covering to B.S.2479.

NOTE: Whatever type of conductor covering is employed and whatever type of impregnant is selected, these shall be tested together as follows:
Six turns of a wire not exceeding 16 S.W.G. (1.70 mm.) insulated with the desired covering shall be wound on a $\frac{1}{2}$ inch (12.7 mm.) diameter mandrel and the coil then removed from the mandrel and immersed in the impregnant at a temperature of 80° C for two hours. The coil shall then be washed in alcohol, straightened and wiped gently with a clean rag. If there is stripping of the insulating covering, that particular combination of insulant and impregnant shall not be used.

(xi) If wire to B.S.156 or B.S.3188 is used, each layer shall be interleaved with paper complying with B.S.698 or with material having equivalent or superior insulating and physical properties. This insulation and that between the windings and any earthed screen shall be capable of complying with the electric strength test appropriate to the highest operating voltage of the windings concerned. Synthetic resin-bonded paper used in the construction shall comply with B.S.1137. The finished winding shall be at least $\frac{1}{16}$ in.(1.6 mm.) below the level of the bobbin flanges.

(xii) Where earthed screens are provided, they shall be of a width at least equal to the

axial winding length. The earthing connection shall be soldered to the screen. The screen shall be assembled with an insulated overlap of not less than $\frac{1}{8}$ in. (3.2 mm.) and shall be free from jagged edges or burrs. The edges of the screen shall be bound with paper, silk or cotton before assembly into the transformer.

(xiii) The coil shall be thoroughly dried and then impregnated in accordance with the instructions issued by the manufacturer of the impregnant. The plant employed shall be capable of maintaining a reduced pressure not exceeding 2 mm. of mercury for periods of 30 minutes. The impregnant shall be a thermo-setting compound requiring a stoving temperature not exceeding 120° C, and shall contain no spirit solvent which is capable of giving off a flammable vapour.

Motors

140. Motors shall comply with B.S. 170 and where accessible shall be of a totally enclosed or screen protected type.

141. Series type motors shall be capable of operating satisfactorily when connected with a supply of 1.06 times the rated voltage with the lowest possible load.

142. Any switch incorporated in the motor frame shall comply with the appropriate parts of the Code including the switch endurance test.

143. Brush caps shall be accessible only with the aid of a tool. Screw type brush caps shall be located on a shoulder or other abutment and shall engage a minimum of three full threads. Alternative methods of securing carbon brushes shall not rely solely on the brush spring pressure for holding the device in position.

144. The short circuit or open circuit of any capacitor connected in circuit with a motor shall not impair the safety of the apparatus.

145. Any motor driven metallic parts which, during their functional use, are liable to come into direct contact with patients shall be completely electrically isolated from the metalwork of the motor by double insulation or reinforced insulation which is capable of withstanding the electric strength test appropriate to the rated voltage of the motor and having adequate mechanical strength.

Batteries

146. Primary cell batteries shall be so arranged that they are readily accessible and can easily be renewed without disturbing other components, wiring, etc.

147. Batteries containing liquids shall be arranged in such a manner that the insulation of the battery and of other parts cannot be impaired by leakage of the liquid. Compartments housing such batteries shall be ventilated to eliminate the risk of accumulation and ignition of gases.

Capacitors

148. Capacitors shall be correctly rated for the voltage, ripple and temperature conditions which are likely to be experienced in normal use and shall comply with the appropriate B.S. specification.

149. The energy retained by capacitors or by any incidental capacitance in the circuits shall not exceed 2 millijoules at any moment after it is possible, e.g. by removal of protective covers, to touch parts connected to these capacitors. This requirement shall be assessed on the assumption that the ON-OFF switch of the apparatus is turned to the OFF position before commencing to remove a cover.

Lampholders

150. Lampholders shall comply with a relevant British Standard or other approved specification.

151. Edison-screw type lampholders shall be so connected that the centre contact is the live pole.

152. Lampholders shall not be used as electric wiring connectors.

Excessive current protection

Fixed apparatus

153. All circuit wiring and components shall be protected against excessive current by means of a correctly rated fuse or an automatic type circuit breaker inserted in each live supply conductor. See Notes (1) and (2) below.

Portable apparatus

154. Over-current protection, e.g. a fuse or circuit breaker, in the live conductor, shall be provided on the apparatus where wiring or components having a current rating less than the supply cord are used and fault current substantially in excess of the current rating of the wiring or components can occur. Where a fuse is used, the fuse rating shall be the lowest available value capable of continuously carrying the current taken by the apparatus. If the nature of the load is such (e.g. a transformer) that higher current surges are likely to occur when switching on, anti-surge fuses shall be used.

NOTE: (1) If, on account of the circuit arrangement, adequate protection cannot be achieved by a single over-current device, sub-circuit fuses or circuit breakers should be incorporated.

(2) It may be impracticable to provide adequate over-current protection on very low voltage circuits and special care should be taken to minimise the possibility of short circuits occurring on these circuits.

Fuses

155. Fuse elements shall be totally enclosed and the fusing factor (see paragraph 42) shall not exceed 2 (except in the case of anti-surge fuses). Fuses shall comply with B.S.1361, 1362, 2950 or other approved specification.

156. The current rating of the correct fuse to be used shall be clearly and indelibly marked on or adjacent to each fuse holder.

157. When fuse renewal can be carried out without the use of tools, live conductors associated with the fuse holder shall be shielded to enable fuse renewal to be carried out without risk of electric shock.

158. Panel type fuse holders shall be constructed or otherwise protected to prevent the ingress of moisture. The line connection terminal of the fuse-holder shall be the one remote from the panel.

Circuit breakers

159. Automatic circuit breakers shall be adequately rated and shall comply with B.S.3871.

Pressure release

160. Apparatus containing liquid or gases under pressure shall be capable of safely withstanding a test pressure equal to not less than twice the maximum working pressure and shall incorporate adequate safeguards against the possibility of build-up of dangerous pressure.

Supply connection

161. The supply connection shall be one of the following:

Portable apparatus

(i) A flexible cord complying with paragraph 169 permanently connected to the main supply terminals.

(ii) An appliance inlet and connector, having a voltage and current rating at least equal to that of the apparatus and complying with a relevant British Standard or other approved specification.

Appliance inlets on apparatus which requires an earth connection and/or incorporates a single pole device for interrupting the supply, shall be non-reversible.

Fixed apparatus

(iii) Permanently installed wiring having a current rating at least equal to the maximum current loading of apparatus. Proper entry facilities, e.g. for a screwed conduit connection, shall be provided in a position convenient to the main supply terminals.

Plugs and sockets

162. Plug and socket connectors, including appliance inlets, which are intended to be connected to mains electricity shall comply with a relevant British Standard or other approved specification. Other types of plug and socket connectors incorporating live parts which are capable of causing electric shock shall be shrouded to prevent accidental contact with live parts, even when the two parts of the connector are separated, or when attempts are made to insert the pins incorrectly.

163. Connectors incorporating plugs or sockets which operate at voltages differing from standard mains voltage shall not be interchangeable with any standard type of mains connector or with any plug or socket device on the apparatus which operates at a higher voltage.

164. Plugs and sockets for use with apparatus or components requiring an earth connection shall incorporate an earth continuity connection having a current-carrying capacity at least equal to that of the supply connections and arranged so that the earth connection is made and broken with the supply connections. Where correct polarity is necessary for safety reasons or for correct functioning of the apparatus, plugs and sockets shall be of a non-reversible type.

165. Where an earth connection is essential for safety reasons, any connector in the earthing circuit shall either be provided with a suitable retaining device to prevent inadvertent disconnection during normal use, or be continuously monitored and so arranged that an audible warning is given should a break in the earth connection occur while the apparatus is in use.

166. Exposed metal parts on plug and socket connectors incorporating live conductors, unless isolated from the live conductors by double insulation or equivalent reinforced insulation, shall have an earth continuity connection with a current-carrying capacity at least equal to that of the live conductors.

167. Where plug and socket devices are necessary for the proper functioning of apparatus, the plug and socket with the necessary leads shall be provided with the apparatus.

168. Plugs or sockets which are intended for use with a flexible cord shall incorporate an effective cord grip which will prevent stress on the terminal connections during normal use and shall also incorporate suitable facilities to prevent undue bending of the flexible cord at the entry point to the plug or socket. Terminals incorporated in plugs and sockets shall comply with paragraphs 80–89 as applicable.

Flexible supply cords and cables

169. Portable appliances shall be provided with a flexible supply cord, at least 9 ft. (3 m.) long, having an outer protective insulating sheath, and

complying with a relevant British Standard. The minimum size of the conductors shall be as follows:

*Up to 2 A	14/.0076 in.	(16/0.20 mm.)
Up to 5 A	23/.0076 in.	(24/0.20 mm.)
Over 5 A but not exceeding 10 A	40/.0076 in.	(30/0.25 mm.)
Over 10 A but not exceeding 15 A	70/.0076 in.	(50/0.25 mm.)

*NOTE: Because of its greater mechanical strength 23/.0076 in. (24/0.20 mm.) flexible cord is preferred for apparatus rated at up to 2 A except for very small lightweight apparatus where it may be necessary to use the smaller size of cord.

170. A three-core cord shall be used for appliances requiring an earth connection and the colour marking of the conductors throughout their length shall conform with the appropriate colour code.

NOTE: From July 1970 the colour code shall be " brown " for the line conductor, " blue " for the neutral conductor, and " green/yellow " for the earth continuity conductor.

171. Where the supply cord passes through the outer casing of the apparatus a properly secured, tapered grommet or equivalent device shall be provided to relieve stress on the conductors and prevent sharp bends and abrasion of the flexible cord at the entry point. The surface of the stress relief device in contact with the flexible cord shall be insulating. Knots in the flexible cord and detachable parts which are easily lost are not permitted for this purpose. Metal helices are not permitted as protection against excessive bending of the flexible cord.

172. Supply cords which operate at voltage of 250 V or less shall not be run in protective flexible metal tubing or sheath where external to the apparatus. If a metallic mesh screen is incorporated it shall be completely protected by an outer insulating sheath and shall be additional to the earth continuity conductor.

173. Supply flexible cords and cables operating at voltages exceeding 250 V shall incorporate an earthed metallic screen as additional protection against the risk of electric shock. The screen shall be bonded to an efficient earthing source at each end and have an outer protecting sheath of insulating material.

Electrode leads and terminals

174. Electrode leads and external wiring between component parts of apparatus which operate at voltages capable of causing a harmful electric shock shall consist of flexible cords having a protective insulating sheath in addition to the functional insulation and shall comply with an appropriate British Standard or other approved specification. The current rating of conductors shall at least equal the maximum working current and the leads shall be capable of withstanding cleaning, disinfecting and sterilizing processes that are liable to be met in normal use without undue deterioration.

175. Live parts of terminal connections associated with electrode leads shall be protected to prevent accidental contact during normal use. Screws, nuts and other small parts shall be arranged so that they cannot become detached in normal use.

176. Where incorrect connection of electrodes can constitute a danger, the terminal connections shall be arranged to prevent leads being incorrectly connected to apparatus.

Electrodes

177. Whenever practicable electrodes and electrode holders shall be insulated to minimise the possibility of accidental contact with live parts during normal use, including during the process of removing or inserting electrodes into electrode holders. The insulation shall also minimise the possibility of unwanted leakage currents whilst electrodes are in use.

178. Electrodes and electrode holders shall be capable of withstanding without undue deterioration cleaning and sterilizing processes which are likely to be encountered in normal use.

Indicator lamps

179. Indicator lamps shall be provided as follows:

(i) On apparatus incorporating non-luminous heaters to indicate when the heaters are switched on.

NOTE: This requirement is not applicable to medical treatment lamps which are covered by B.S.3232.

(ii) To indicate when the supply is switched on on portable apparatus which is intended to be connected to a supply exceeding 15 V and having no manually operated switch control to power supply (see paragraph 106).

(iii) To indicate when the output circuit is energised where an inadvertent or prolonged operation of the output circuit could constitute a danger.

180. The indicator lamps shall conform to the following colour code:

(i) Green, or alternatively a plain neon lamp behind a clear lens cover, to indicate when the electrical supply is switched on.

(ii) Red to indicate overheating or other dangerous conditions.

(iii) Amber or white to indicate safe operating conditions.

NOTE: Green is the preferred colour to indicate when the electrical supply is switched on, and with equipment incorporating low voltage supplies the provision of a green indicator lamp presents no difficulty. Neon lamps having a green fluorescent coating are currently available but the light output and

colour lasting properties may be less satisfactory and for this reason the alternative of a plain neon lamp with uncoloured lens cover has been given.

181. Indicator lamps shall be clearly visible under all normal operating conditions and shall be protected against mechanical damage by a lens cover. They shall be of a neon type or shall be filament lamps run at not more than 80 per cent of their rated voltage.

Colour coding of connections

182. Wiring at mains potential including internal wiring connections between components shall be colour coded in accordance with the " Regulations for the Electrical Equipment of Buildings " issued by the Institution of Electrical Engineers. The colour coding of electronic apparatus is dealt with in B.S.2311 and it is recommended that this standard be complied with, where it is applicable.

Patient circuits

183. Circuits which include electrodes or other metal parts that are liable to come into direct contact with patients during normal use shall be isolated from power circuits so as to prevent any possibility of dangerous interconnections. Where insulation alone forms the separation, double insulation appropriate to the maximum voltage present shall be used or equivalent reinforced insulation where the use of double insulation is impracticable. The insulation shall be capable of complying with the electric strength test appropriate to the maximum working voltage.

184. Direct currents in the microampere range from a source having an open circuit potential of 0.5 V or more and flowing into skin tissue from conducting electrodes can cause the destruction of tissue, leaving an open sore. The effect depends upon current density in the tissue and the length of time for which it is applied and examples of equipment which can produce this condition are enuresis alarms and some E.C.G. apparatus which include biased transistors in the electrode circuits.

185. Appropriate steps should be taken to minimise the flow of d.c. through electrodes or other conducting parts that may come into direct contact with the patient. For physiological monitoring apparatus such as electro-cardiographs, the maximum direct current which can flow between electrodes and between any electrode and " earth " should be limited to 10 microamperes. For enuresis alarms the electrodes should be so arranged as to make unlikely simultaneous direct bodily contact with both electrodes, and the maximum direct current which can flow between the electrodes under the worst conditions (electrode short circuit) should be limited to 100 microamperes.

186. These limitations do not apply to equipment such as stimulators where the flow of direct current is essential for therapeutic or diagnostic purposes.

NOTE: The inter-electrode spacing of thermionic valves when used in accordance with the manufacturers' recommended operating conditions, usually provide adequate circuit spacing.

187. Apparatus having potentially lethal outputs under conditions in which they are used (e.g. cardiac defibrillators and electro-convulsive therapy apparatus) shall have both poles of the output circuit completely disconnected from its energising source except during the period of treatment. The duration of treatment shall be indicated as described in paragraphs 124 and 125.

188. Circuits to which patients may be connected shall be earth-free unless an earth connection is necessary for the proper function of the apparatus or for safety reasons.

NOTE: When surgical diathermy is in use, the patient's body should be maintained at a potential as near as possible to earth to minimise the risk of accidental burning due to contact between the patient's body and metal objects which are earthed, or virtually so because of their appreciable electrical capacitance to earth. This can be accomplished by a suitable capacitor having a low impedance (not exceeding 10 ohms) at diathermy frequency but a high impedance at mains frequency. This capacitor should be mounted within the equipment and connected between the patient terminal(s) and the equipment earth.

Because of the impedance of the patient's body and the contact impedance at the point of contact between the plate electrode and the body, it is impossible to avoid some difference in potentila between parts of the body and earth. Where other apparatus having a direct electrical connection to the patient is used at the same time as diathermy, it is important that the patient circuit of such apparatus is earth-free to reduce the possibility of the electrodes and leads forming a return path for diathermy currents and causing a burn at the points of contact with the patient.

Earth-free working is also important for circuits of stimulators and monitoring equipment having direct electrical connection to the heart because of the very small current which can cause ventricular fibrillation when passed directly through the heart. Avoidance of an earthing connection will reduce the chance of stray leakage currents flowing through the heart from other equipment which may be connected to the patient at the same time. In this connection precautions should also be taken to prevent the possibility of stray currents reaching the heart through a conducting column of liquid, e.g. a catheter filled with a saline solution.

Output limitation

189. The rated output should not greatly exceed the highest value that is likely to be required for the treatments for which the apparatus is designed.

190. The design shall be such that accidental short-circuit of the output will not cause significant damage

to the apparatus, protection being provided either by incorporating current limiting arrangements within the circuits, or the provision of overload protection in the form of fuses, thermal cut-outs or circuit breakers.

NOTE: It is recommended that the resetting or replacement of such protective devices is possible only when the output circuit is disconnected or the output control is returned to zero, to prevent the sudden restoration of supply causing an excessive output level.

191. Where the apparatus is a multi-purpose unit designed for providing both low intensity and high intensity outputs for different treatments, appropriate steps shall be taken to minimise the possibility of a high intensity output being selected accidentally.

NOTE: This can be achieved by providing separate output connections or by the provision of a separate manually operated interlocking device.

192. Apparatus such as defibrillators and electro-convulsive therapy units which are potentially dangerous in the hands of inexperienced persons shall have a conspicuous indelible notice drawing attention to the fact that the apparatus is capable of delivering potentially dangerous outputs and should only be used by persons who have received proper instructions on its correct use.

193. Suitable indelible operating instructions shall be provided on apparatus which is liable to be used in an emergency, such as cardiac defibrillators and cardiac pacemakers

Radio and television interference

194. Apparatus which generates or is liable to generate fortuitously electromagnetic energy shall comply with Statutory Instrument 1895, Wireless Telegraphy (Control of Interference from Electro-Medical Apparatus) Regulations, 1963.

Mechanical stability

195. Portable apparatus shall be capable of remaining stable under any condition of normal use and shall satisfy the following stability test:

When placed in any normal position on a plane inclined at an angle of 15° to the horizontal plane, the apparatus shall not over-balance. Where apparatus is fitted with castors they shall be temporarily fixed in their innermost position when carrying out the test.

With the appliance placed on a smooth level floor, it shall not be possible to overturn it with a steadily increasing pull, applied horizontally in any direction on a horizontal plane corresponding with the point of attachment of the flexible cord to the appliance.

Guards

196. Surfaces which, in an ambient temperature of 25° C, are liable to exceed a temperature of 85° C, shall be guarded or similarly protected.

197. Guards which are necessary to prevent contact with live conductors or with hot surfaces shall be removable only with the aid of a tool.

Marking

198. There shall be permanent, clearly legible marking on the apparatus, giving the following details, as appropriate:

(i) Name of manufacturers or supplier.

(ii) Identification of type of construction on Class II apparatus; e.g., double insulated.

(iii) Rated voltage or voltage range.

(iv) The kind of current, where this is necessary, for the safe use of the apparatus, e.g. a.c. or d.c., and number of phases if more than one.

(v) Supply frequency, where this differs from 50 c/s. (50 Hz).

(vi) The rated input in watts, kW, VA or kVA.

(vii) The rated output of power (where applicable) and the peak output maximum operating time and recovery time where apparatus is rated for intermittent duty only. The output frequency shall be given where this differs from the input frequency.

(viii) Diagram of connections on apparatus having more than two supply terminals, where necessary to clearly indicate the correct supply connections. The diagram shall be located near the supply terminals.

(ix) On apparatus having components which operate at potentials exceeding 250 V, the warning "danger high voltage" shall be clearly indicated on covers giving access to these components.

(x) Ambient temperature limits where outside the range 20±5°C.

Endoscopic and cautery apparatus

General

199. The rated voltage of circuits (a.c. or d.c.) which are intended to provide a continuous supply for endoscopic or cautery apparatus shall not exceed 6 volts open circuit and 4 volts at the maximum rated current.

200. Each circuit shall be earth free and be a completely separate energy source, e.g. separate winding of a transformer or supplied by means of a separate battery so that there is no electrical interconnection between circuits which are used for supplying endoscopic or cautery apparatus.

Photo-endoscopic circuits

201. Flash lamp supplies shall be obtained by capacitor discharge and all poles of the lamp circuit shall be isolated from the power supply circuit during the discharge period. The charging circuit shall in turn be electrically isolated from mains electricity.

202. The maximum energy per impulse shall not exceed 100 joules and the peak voltage shall not exceed 350 volts.

203. Lamp envelopes shall be coated with an electrically insulating protecting film to minimise the risk of electric shock and injury to the patient in the event of a failure of the envelope. Coaxial wiring and connections shall be used and the outer conductor shall be sheathed with insulating material appropriate to the maximum rated voltage of the circuit.

204. Plug and socket connections shall not be interchangeable with those of any other source of supply which could constitute a danger.

Endurance test

205. Apparatus shall be capable of operating at 1.1 times the maximum rated voltage with any operating controls adjusted to positions corresponding to maximum loading and, where interchangeable components are provided, with the apparatus fitted with those which are most unfavourable, for a period as indicated below:

(i) Continuously rated apparatus	5 hours.
(ii) Intermittently rated apparatus	50 times, for the maximum operating time marked on the apparatus, allowing the minimum specified rest period between the operating periods.

206. Apparatus shall be capable of complying with the test in any ambient temperature within the range 20±5°C, or at the maximum temperature where special higher ambient temperature limits are marked on the apparatus and at the minimum temperature where special lower ambient temperature limits are marked on the apparatus, where this is less favourable to the apparatus.

207. At the conclusion of the test the maximum operating temperatures shall not exceed the values given in paragraphs 211 and 212 and the apparatus shall be capable of complying with the leakage current test described in paragraphs 208 and 209. The apparatus shall be satisfactory for further service.

Leakage current test

208. The apparatus shall be operated at the maximum rated voltage. When the maximum operating temperature conditions are reached the leakage current shall be measured as follows:

(i) *Class I apparatus*

Between live parts of the power supply circuit and exposed metal parts. Figure 3 shows a circuit diagram for testing Class I apparatus.

(ii) *Class II apparatus*

Between live parts of the power supplies circuit and accessible metal parts or metal foil on exposed insulated parts, also between live parts and functionally insulated non-accessible metal parts. Figures 4 shows a circuit diagram for testing Class II appliances.

(iii) Apparatus with multi-phase supply connections or apparatus having alternative means of connection shall be tested in the least favourable condition for the connection to the supply.

209. The leakage current shall not exceed the values specified in paragraphs 77 and 78.

Maximum operating temperatures

210. The temperature of the undermentioned parts shall not exceed the values specified, when apparatus is operating at its maximum rated current, for a sufficient time for steady temperature conditions to be achieved or for any terminal safety device to have operated. For this test, steady is defined as not changing by more than one degree centigrade, in 30 minutes. The tests should be carried out in an ambient temperature within the range 20±3°C using a temperature-sensitive element, e.g. a thermocouple or thermistor with its associated indicating instrument in accordance with B.S.1041.

External parts	*Temperature*
211. (i) Metal parts, including handles, which may be gripped in normal use	55°C
(ii) Vitreous or glassy surfaces which may be gripped in normal use	65°C
(iii) Other non-metal parts	75°C
(iv) Parts which may be held for short periods only, metal ..	60°C
(v) Parts which may be held for short periods only, vitreous or glassy	70°C
(vi) Parts which may be held for short periods only, other non-metallic surfaces	85°C
(vii) Metal parts which may be touched inadvertently	85°C
(viii) Contact pins of appliance connectors, terminals, etc... ..	85°C

Insulation

212. (i) Natural rubber	60°C
(ii) Varnished cambric	80°C
(iii) Butyl rubber	95°C

(iv)	Silicone rubber	150°C
(v)	Phenolic mouldings, mineral ..	100°C
(vi)	Fibre	90°C
(vii)	Wood	95°C
(viii)	Impregnated wood	110°C
(ix)	Asbestos or glass fibre varnished or impregnated with synthetic resin varnish	135°C
(x)	Asbestos or glass fibre varnished or impregnated with alkyd, epoxy and similar resins ..	160°C
(xi)	Asbestos or glass fibre varnished or impregnated with silicone ..	185°C
(xii)	Thermo-plastics (polyacrylates, polyethylene, polystyrene and normal grades of p.v.c.) ..	70°C
(xiii)	Class Y*	90°C
(xiv)	Class A*	105°C
(xv)	Class E*	120°C
(xvi)	Class B*	130°C
(xvii)	Class F*	155°C
(xviii)	Class H*	180°C

*Details of insulating materials covered by these classes are contained in B.S.2757.

NOTE: These temperatures are based on an ambient temperature of 20°C. Where the ambient temperature of the test room differs from this value, the maximum operating temperatures quoted above should be adjusted accordingly.

VI. Guarantee

Guarantee of construction

213. Suppliers who claim that apparatus has been manufactured to comply with the Safety Code shall be prepared to give an assurance to purchasers to this effect. When a purchaser requests visual proof of compliance with the test requirements, his representative shall be permitted to witness the carrying out of the specified tests at the manufacturers' works. In the event of a dispute, the ruling of an independent chartered engineering consultant shall be accepted. Alternatively, the apparatus shall be submitted to an approved testing authority.

214. The Department of Health and Social Security does not undertake the general approval of electromedical apparatus but is prepared to assist manufacturers and hospital authorities with any specific technical queries arising from the application of the code.

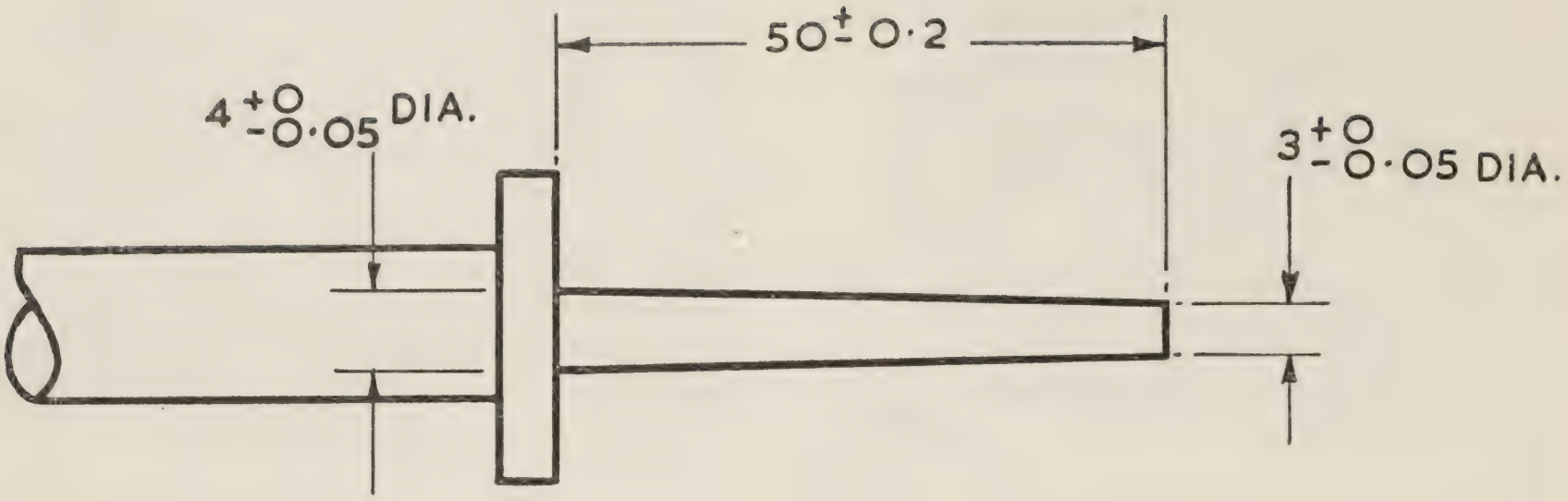
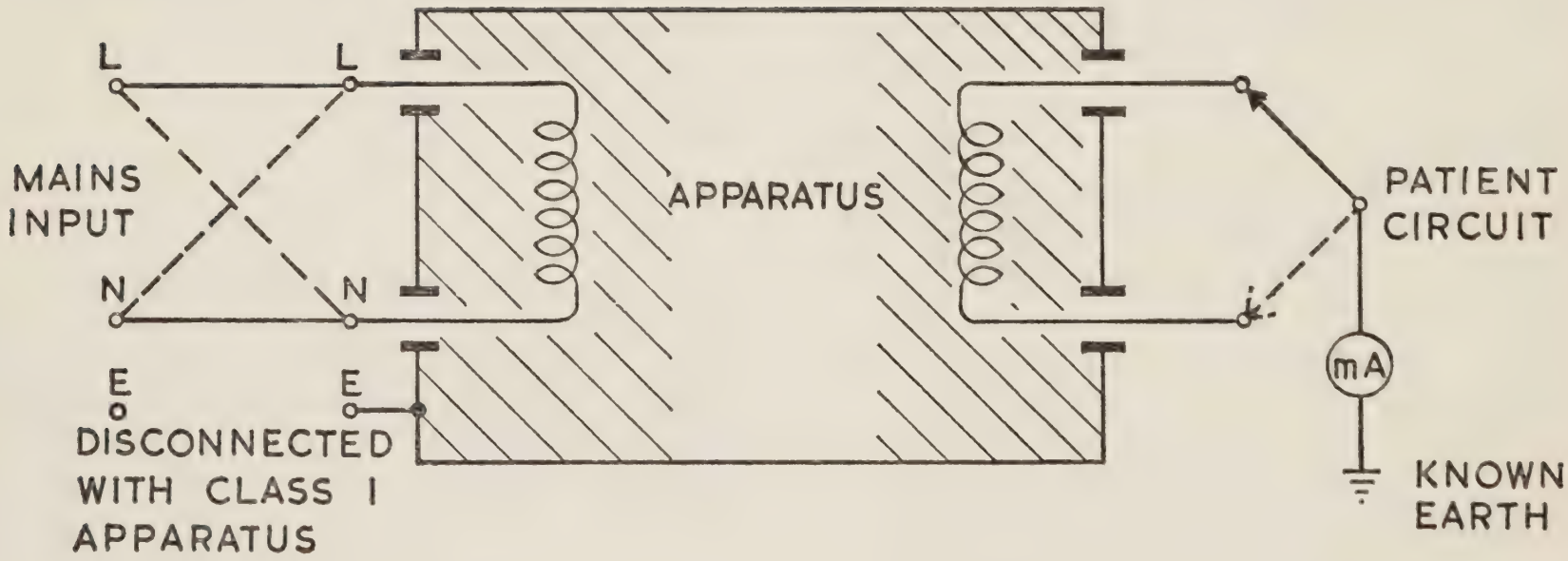


FIGURE 1. Test pin.



TEST WITH BOTH CORRECT AND REVERSED POLARITY

LIMITS

1. GENERAL LIMIT 0·5 mA
2. LIMIT ON EQUIPMENT WHICH MIGHT BE USED IN CONJUNCTION WITH A WIRE ELECTRODE IN THE HEART 0·1 mA

FIGURE 2. Schematic diagram for testing leakage current between supply and utilisation circuits.

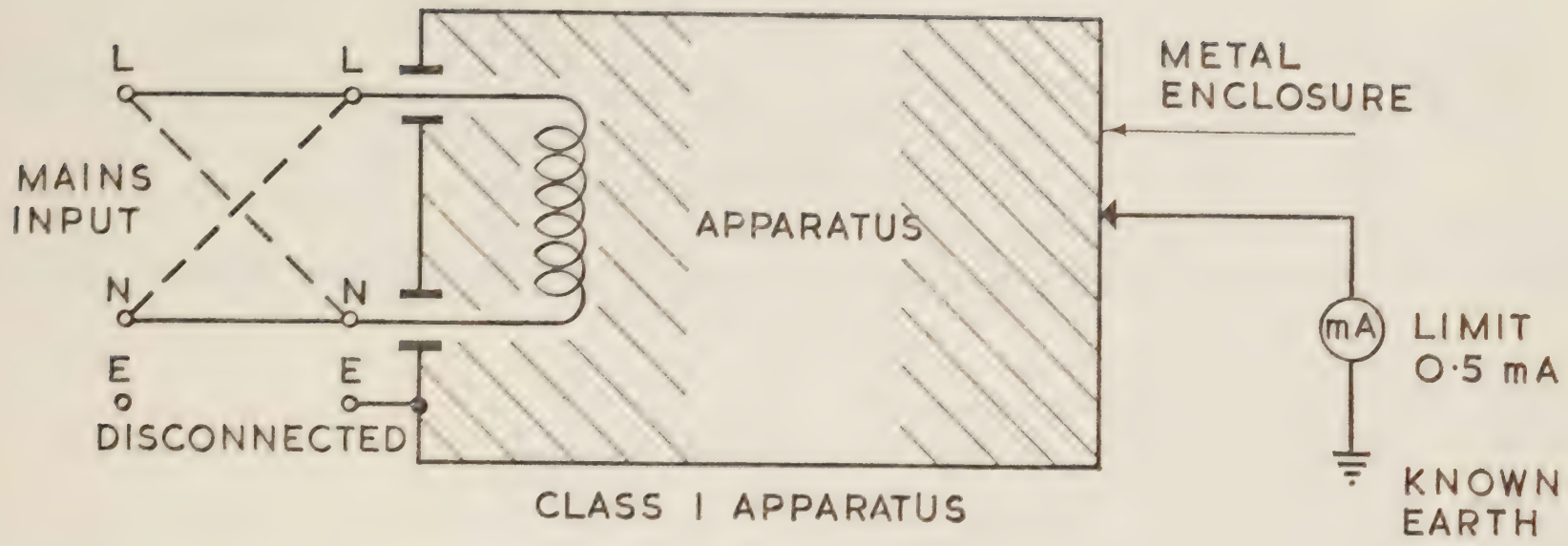


FIGURE 3. Schematic diagram for testing leakage current to exposed metal parts.

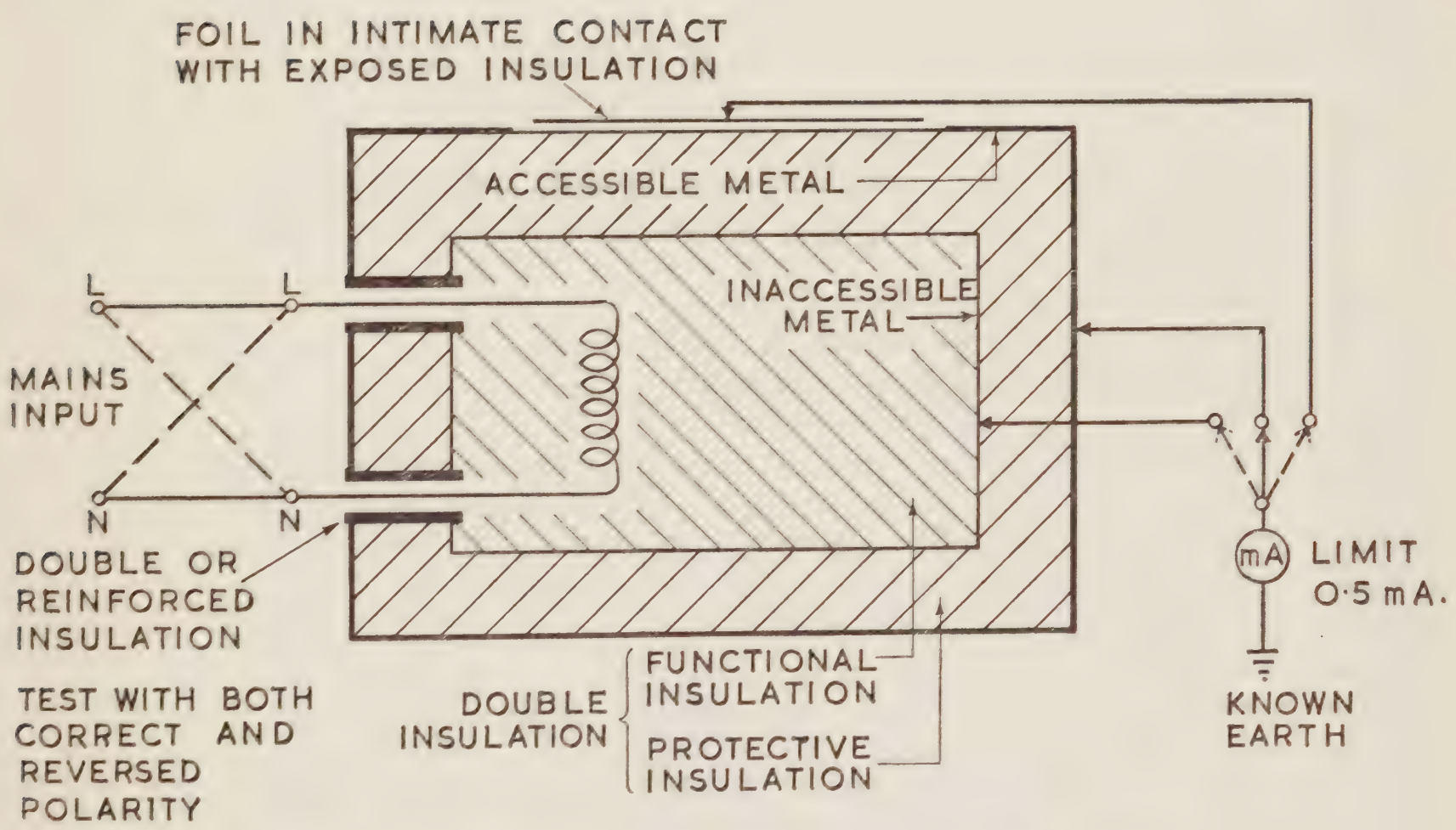


FIGURE 4. Schematic diagram for testing leakage current Class II apparatus.

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B.S.2848. Flexible insulating sleeving for electrical purposes.

B.S.2849. Memorandum on therapeutic x-ray equipment.

B.S.2904. Hospital sterilizers. (Boiling water type.)

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B.S.2950. Cartridge fuse-links for telecommunication and light electrical apparatus.

B.S.3028. Electric vacuum cleaners for use in hospitals.

B.S.3042. Standard test finger (for checking protection against electric shock).

B.S.3061. Electrically heated incubators for babies.

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